Citation: Ashford S, Slade M, Turner-Stokes L (2013) *Conceptualisation and development of the Arm Activity measure (ArmA) for assessment of activity in the hemiparetic arm*, Disability & Rehabilitation, **35**, 1513-1518.

Development of the Arm Activity Measure (ArmA) for assessment of activity in the hemiparetic arm

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Keywords: function, upper limb, outcome measure, rehabilitation.

Abstract

Purpose

To develop a patient reported outcome measure (PROM) of active and passive function in the hemiparetic upper limb.

Methods

Analysis of items in existing measures was taken from a systematic review of the literature. Analyses of common goals for treatment were also identified from a patient cohort series (n=16). Consultation with physiotherapists, occupational therapists, rehabilitation nurses and rehabilitation physicians during a 3-round Delphi process (n=10) was then undertaken followed by a confirmatory survey with a larger group of clinicians (n=36). Preliminary piloting and evaluation with patients and carers (n=36) was then undertaken.**Results**

27 items were initially identified for inclusion in ArmA – 7 passive function and 20 active function. Through Delphi consultation with clinicians the number of items were refined to 7 passive function and 13 active function.

Conclusions

Content and face validity have initially been addressed within the development process. The next phase of development will involve formal evaluation of psychometric properties. The ArmA is designed to be used to measure the passive and active function improvements following upper limb rehabilitation interventions such as focal spasticity intervention.

Word count 200

Introduction

Outcome measurement is applied in rehabilitation to determine the effectiveness of interventions. Whether in clinical practice or for research, measures need to be valid, reliable and responsive to clinically relevant change. Global measures of function in daily activities, such as the Barthel Index [1], provide a general assessment of independence but are often unresponsive to focal interventions in the upper limb. Small changes, which may be extremely important to the patient and/or their carers are easily lost amongst the larger number of unchanging items [2].

Measures of active and passive function are required which capture outcome following focal interventions (such as botulinum toxin-A intervention) in the upper limb. Following stroke or brain injury, goals for rehabilitation of the hemiparetic upper limb may be: **to restore active function**, if there is return of motor control or **to improve passive function** making it easier to care for the limb (e.g. maintain hygiene) if no motor return is possible. Both active and passive function have potential for improvement following spasticity intervention including botulinum toxin-A with passive function improvements being much more common [3]. Any comprehensive outcome measure for spasticity intervention needs to assess both active and passive function to fully reflect the changes seen post intervention, despite active function changes being comparatively rare [4].

A systematic review [5] identified six measures (including four versions of the Motor Activity Log - MAL), which had been used in the published literature to evaluate function reflective of real-life or actual performance. The six measures appeared to fall

broadly into a hierarchy of increasing difficulty. The Leeds Adult Spasticity Impact Scale (LASIS) evaluates passive function and low-level active function, such as using the affected hand to hold and stabilise objects. The MAL and ABILHAND were more comprehensive (and consequently complex) measures for active function, evaluating a wide range of activities, including unilateral and bimanual function.

The systematic review identified a reasonable selection of validated tools available for the evaluation of 'real-life' active function in the hemiparetic upper limb. None provide a comprehensive assessment of both active and passive function. Depending on difficulty of the goals for treatment, clinicians could select from the measures presented in this review but would need to be aware of the limitations in psychometric evaluation for some of these measures as discussed in that work. The need for a self-report measure of active and passive function for application in the hemiparetic upper limb following focal spasticity intervention was identified. In this paper, the development of the measure is reported.

Aims

The aims were to develop a self-report measure to assess both active and passive function in the hemiparetic upper limb following focal rehabilitation interventions, and then to confirm face and content validity by investigating item relevance for professionals, patients and carers.

Method

The Arm Activity Measure (ArmA) was developed using a modified Delphi Consultation, followed by wider consultation with other clinicians, patients and carers and pilot testing. A sub-scale was developed for both active and passive function. A Delphi approach uses an iterative consultation to measure opinion from identified experts [6]. The pre-existing items from the systematic review and the patient-identified items were used as a starting point for the process, rather than initial generation of items using the Delphi technique. Modified Delphi consultation was selected because it provides anonymity to participants and reduces personality based influences such as the impact of socially dominant individuals on the consensus process [6, 7]. Finger and colleagues consider the Delphi method to have four key characteristics: anonymity for those participating; iteration of concepts; statistical group response based on frequency of selections (in this instance item selection); and informed input from expert participants [7]. The literature provides no definitive recommendation on panel size, which have ranged greatly in different studies between 10 and 1685 [8] and in the rehabilitation literature from 15 [9] to 263 [7]. Raine suggests that good results can be obtained with between 10 and 15 panel participants where the group is homogenous, and that smaller groups such as this are also more likely to retain group members [9].

In Delphi Consultation, consensus is deemed to have been identified when the votes from respondents fall within a pre-defined range. For example, Raine used an 80% response level for acceptance of an item, where 80% of respondents agree with the item or change to the item. A range of acceptance levels can be found in the literature

between 55 and 100 percent [10, 11]. In this study, the level was set at 60% consensus for exclusion or inclusion of items.

Development comprised two stages. Stage 1 used a Delphi consultation process to initially develop the measure. Stage 2 used a wider consultation to confirm findings with other clinicians in addition to patients and carers.

Participants

Stage 1 used a purposive sample of experienced clinicians. Participating clinicians worked in two regional rehabilitation units, two district rehabilitation services and a community rehabilitation team within the London Region. The panel of clinicians included physiotherapists (n=4), occupational therapists (n=4) and rehabilitation medicine physicians (n=2). All therapists were either clinical specialist or senior level and the rehabilitation medicine physicians were both consultant level.

Stage 2, clinicians group consisted of specialist physiotherapists, occupational therapists and rehabilitation nurses none of whom had been involved in earlier stages of development or evaluation. The invited physiotherapists were all identified from the UK Physiotherapy Adult Spasticity Forum, with the consultation document sent to the whole membership (n=58). Occupational therapists were identified through initial contact with the physiotherapists and worked with them in specialist neurological rehabilitation services, with involvement in spasticity management. Rehabilitation nurses were identified from rehabilitation services in North West London NHS Trust and worked with patients with upper limb activity limitation following stroke and brain injury.

Patients and carers were identified from those receiving inpatient, outpatient or outreach spasticity management input from North West London, Hertfordshire and Bedfordshire through the Regional Rehabilitation Service.

Procedure

The process of development comprised initial drafting of the measure, initial item reduction using modified Delphi consultation (stage 1), wider consultation with clinicians and pilot testing with patients and carers (stage 2)

In stage 1, three rounds of Delphi consultation were planned to enable the feedback of comments to the group. Item prioritisation by group participants, in light of the feedback, was then possible to enable decisions on inclusion or exclusion of remaining items. The approach to initial item reduction was to use a clinical prioritisation approach within the Delphi framework to prioritise items based on clinical opinion. This approach was shown to be effective in the development of the Quick DASH, resulting in a shorter, clinically feasible measure with items prioritised by clinicians thought to have greater face validity [12].

Delphi Consultation Round 1: The first draft was generated from two sources a systematic review and patient identified items. Items were then presented to the expert clinicians. The list was distributed by post or electronic mail. Respondents were asked to identify: (a) items which were important to include in a measure of active and passive arm function from the list; (b) items from the list, which should be excluded along with the reason for exclusion; (c) any items that were not on the list which were of particular

importance and explain why they should be considered for inclusion. Once the comments had been returned, participants were, where necessary, contacted to clarify any points and ensure no issues had been missed. The initial list of items was revised in light of these findings to produce a revised short list for round 2.

Delphi Consultation Round 2: The revised list of items was then returned for further comment and verification, consisting of the original list and the revised short list. Respondents were asked to comment again on the items repeating the previous process.

Delphi Consultation Round 3: The results from round two of consultation were sent out again to the same group, consisting of the original list (round 1) and the further revised short list from round 2. The respondents were asked to confirm the selection of items, with the full list of possible items available for reference. Once the comments had been returned, participants were, where necessary, contacted to clarify any points and ensure no issues had been missed.

Following consultation round 3, a draft measure was constructed using the items identified by the group.

Item confirmation by clinicians: Consultation was then undertaken through e-mail or postal consultation with physiotherapists, occupational therapists and nurses for the item confirmation group. Item confirmation was undertaken because further confirmation of content validity in a larger group of clinicians would strengthen and reconfirm the findings. In addition the wider consultation allowed for the inclusion of nurses who were a professional group not included in the Delphi consultation and enabled this possible limitation to be addressed.

Patients and carers were asked to comment on draft ArmA items by responding to the same consultation document as the item confirmation group and were also asked to complete the ArmA.

The consultation document consisted of the draft ArmA and the original list of items from the systematic review and patient identified items. Respondents were asked to identify: (a) items not included in the draft ArmA from the original list which should be included; (b) items included in the draft ArmA, which should be excluded along with the reason for exclusion; (c) any items that were not included in the draft ArmA or the original list which should be included and explain why. Respondents were also asked to comment on the way in which items were scaled.

Respondents who had not returned the consultation document within two weeks were contacted again and a new consultation document sent where required. If they had not returned the consultation document following a further two weeks, they were contacted a third time, after which time follow-up was discontinued.

The responses were then compared with the modified Delphi consultation results. If new items were presented these were considered provided they were identified by more than one respondent, either clinician, patient or carer. The researcher reviewed all comments and made decisions on changes to ArmA based on (1) issues raised by multiple respondents, or (2) issues corresponding to findings from the systematic review. Decisions about items were then discussed with a colleague for concordance before changes were made. This process resulted in the finalised version of ArmA.

Ethical approval for the research programme was received, (COREC number 05/Q1604/110).

Results

The results for reduction of items using modified Delphi technique at stage one and the confirmation and pilot testing of ArmA at Stage two.

Stage 1 - Delphi Consultation

All 10 clinicians initially approached returned the round one consultation document. Following round one, 48 active function items were excluded and 4 passive function items. Consensus for exclusion was between 60 and 100% (6-10 clinicians). Table 1 shows the initial short list of items following round one (the initial full list of items is shown in Appendix 1).

Insert Table 1 about here

The table also shows the measures from which the items originate or identifies that they were patient selected and the broad anatomical region of the arm addressed by each item. During round one, a passive function item, 'Cleaning around the elbow' was removed. This item was removed on the recommendation of eight members of the consultation group (80%), because it was identified as not being relevant for many patients. However, clinicians may not have understood this item to be referring to the elbow crease as well as the dorsal surface of the elbow. Clinically this item is important for patients with flexor spasticity at the elbow.

All 10 clinicians again returned the round two consultation document. A further six active function items were removed following round two. Consensus was between 60% and 80% (6-8 clinicians) for removal of these items. Items not in bold in table 1 were removed.

All 10 clinicians returned the final round three-consultation document. No further items were excluded and there was between 80 and 100% (8-10 clinicians) consensus for the inclusion of the items chosen. One item which had initially been removed; 'use a key to unlock the door' was re-inserted with the agreement of 80% (8/10 of clinicians (see table 1, item marked with '+').

Stage 2 - Item confirmation

A total of 58 questionnaires were sent to clinicians and 36 (62%) were returned. Respondents comprised 25 (69%) physiotherapists, 6 (17%) occupational therapists and 5 (14%) nurses.

Thirty-two questionnaires were posted or directly presented to 16 patients and 16 carers. Thirteen questionnaires were completed in each group (81%). Table 2 displays the characteristics of the patients and carers returning questionnaires.

Insert Table 2 about here

Recommendations by clinicians, patients and carers (respondents) for the exclusion and inclusion of items following item confirmation are presented in table 3.

The majority of items were not considered by respondents for removal (n=12), of the other items only one had more than two 'votes'. Five items from the additional list provided, were recommended for inclusion. The specific modifications and the items changed are detailed below.

Modifications

Several modifications resulted from the wider consultation with clinicians, patients and carers. The active function item 'Wash your back' was removed and replaced by 'Tucking in a shirt', since five of the respondents identified that washing your back is done by many able bodied people using an aid, which concurred with views expressed by clinicians during item reduction. Two additional items were added. The 'Effect of the affected arm on balance when walking' was added following comment by six respondents. Two clinicians considered this item to potentially fit in either passive or active function, since although walking is active; the effect of the arm is passive. However, the other four respondents felt it should be in the active function sub-scale. The task 'Hold an object still while using the unaffected hand' was also added following support from seven respondents.

The term 'Within the last week' was replaced with 'In the last seven days'. The instructions for completion of the two main sections were further refined. The final measure consists of two domains, active and passive function. Passive function contains 7 items. Active function contains 13 items. Figure 1 displays a summary of the changes to items through the different stages of development.

Insert Figure 1 here.

Based on the findings of the systematic review the method of scoring items was adopted from the final six measures identified. The method comprised completion based on activity over the preceding 7 days and was scaled on a five point ordinal scales. This method of scaling responses was adopted as the method for the draft ArmA.

Discussion

The modified Delphi consultation ensured content validity, due to the experience of the clinicians in this area of practice and therefore appropriate reduction of items. Item confirmation with wider consultation of clinicians in spasticity management confirmed the selection of items, and also enabled some modification to take place.

Selection of all clinical groups could have been enlarged to ensure a true national survey for the item confirmation by approaching the respective professional bodies or special interest groups [10]. Breadth of experience among the clinicians may also have been improved by selection through a professional organisation. This approach would have given more support to the content validity of the measure and may have led to a larger consultation with a more consistent national focus. The group selected was also biased towards physiotherapists and although this professional group undertake much upper limb assessment, they are certainly not the only profession involved. However, given that physiotherapists are most commonly involved in management of spasticity in the UK the approach taken was adequate and produced comprehensive comments.

The group pilot testing the questionnaire was relatively small but it is unclear if increasing this would make a significant difference to achieving feedback that is more

informative. A more representative sample could however have been considered. However, this limitation, while important considerations, does not invalidate the pilot testing applied for the ArmA, which was sufficient to enable subsequent psychometric testing.

A possible limitation of prioritising the items generated using the Delphi process and wider consultation is that a set of homogeneous items will be produced, which risks losing the uniqueness of the broader range of items important for hierarchical scaling [13]. Homogeneity may be a strength in supporting unidimensionality (in a single or multiple dimensions), but a group of very similar items may also lead to a set of items of similar difficulty [14, 15]. However while this is a concern, in practice it may be less significant because items selected were focused on lower level active function more likely to change in a patient group undergoing spasticity intervention, which was the focus of the measure developed.

Other approaches to evaluation of the draft ArmA (7 passive and 13 active function items) by patients and carers could have been considered. Such approaches could have included structured interviews [16, 17] or focus groups [18, 19]. Structured or semi-structured interviews or focus groups may obtain more detailed and expansive feedback from respondents than asking for written feedback as was the case in this review [18].

User involvement in ArmA development was at a consultation level rather than full integration of users into research question generation and project design now being incorporated in some studies [20], particularly in the area of Patient Reported Outcome Measures (PROMs). Another possibility in ArmA development was the inclusion of

users at an earlier stage in commenting on the manner and theoretical conception of measurement [21]. However, the approach taken in the ArmA development has resulted in a measure, which does incorporate items important to patients and cares as evidenced in the pilot testing.

In conclusion, the use of Delphi consultation with the addition of further clinician and patient involvement has resulted in a measure, which should provide important clinical information and be feasible in practice as well as having acceptable psychometric properties following testing. The process of item selection, reduction and confirmation was comprehensive and while limitations to the methodology are present, the overall process had a high degree of rigour ensuring confidence in content validity of the ArmA measure produced.

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Table 1 Initial short list of passive and active function items (round 1), mapped back onto the systematic review measures why?

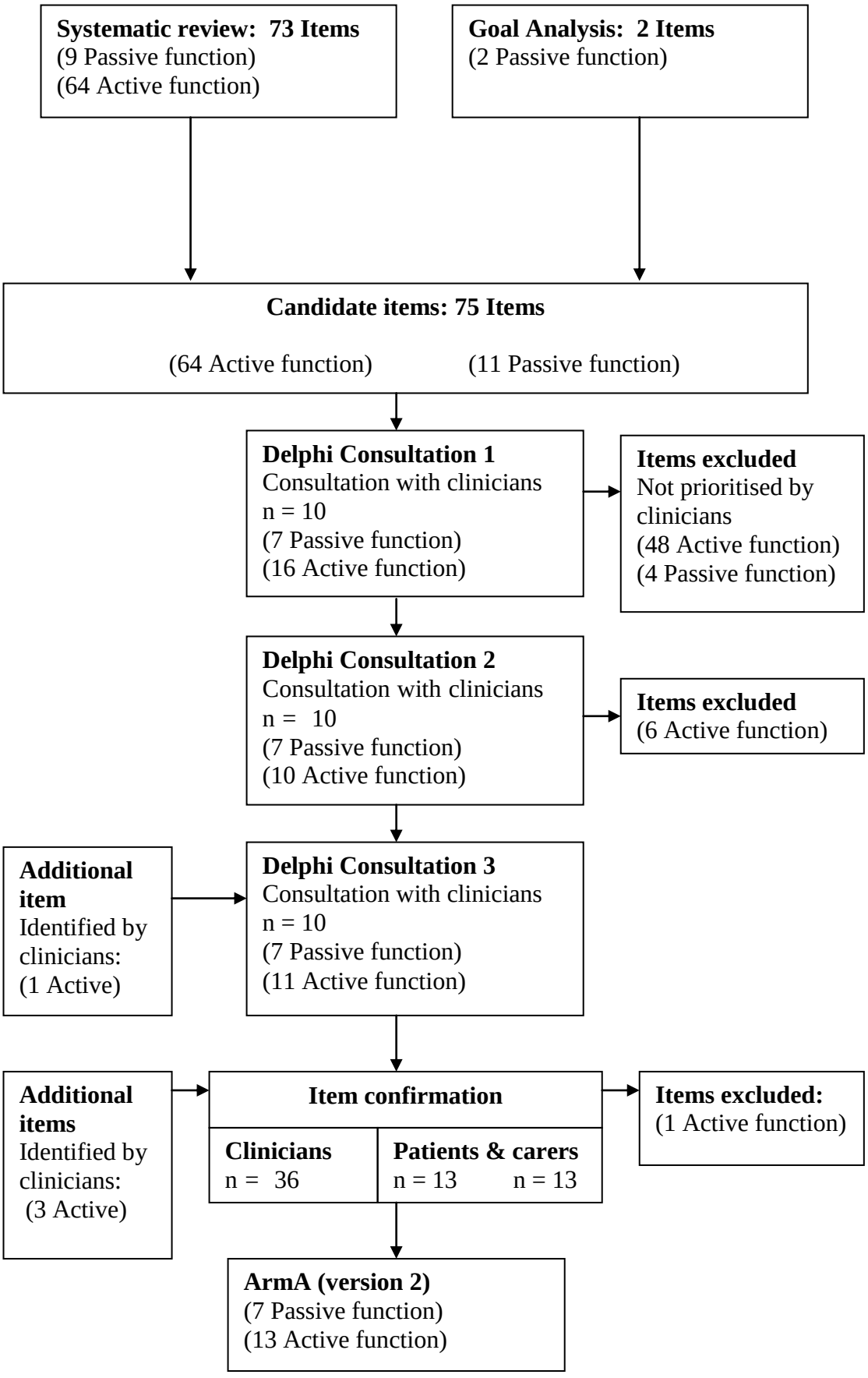
Functional Items	Patient Identified	LASIS	MAL-14	MAL-26	MAL-28	MAL-12	ABIL-HAND	Proximal, Distal, Whole arm
Splint application	*							Whole arm
Positioning the arm comfortably	*							Whole arm
Putting on a glove		*						Distal
Cutting fingernails		*						Distal
Cleaning the armpit		*						Proximal
Cleaning the palm		*		*				Distal
Putting arm through coat sleeve or dressing the arm		*	*	*				Whole arm
Eat with a knife and fork			*	*	*	*		Whole arm
Pick up a glass, bottle, or can			*	*	*	*	*	Whole arm
Brush teeth			*	*	*	*	*	Whole arm
Use a key to unlock the door+			*	*			*	Whole arm
Comb hair			*	*	*	*	*	Whole arm
Pick up a cup by the handle			*	*		*		Distal
Write on paper					*	*		Distal
Carry an object in the hand			*	*				Whole arm
Dial a number on the phone				*	*		*	Distal
Open a jar						*	*	Distal
Pick up phone					*			Whole arm
Put on T-shirt							*	Whole arm
Do or undo buttons on clothing				*			*	Distal
Do or undo a zip				*			*	Distal
Drink from cup/mug							*	Whole arm
Wash your back							*	Whole arm

Items in bold indicate those retained at the end of round three of item reduction – modified Delphi consensus; Item marked with a + was initially excluded.

Table 2 Demographic information of patients (n=13) and carers (n=13)

	Characteristics	Patients	Carers
Age of patients (years)	**Median (range)**	48.5 (30-64)	-
Gender	**Male**	8 (62%)	-
	Female	5 (38%)	-
Ethnicity	**White**	10(77%)	-
	Black	1 (8%)	-
	Asian	2 (15%)	-
Primary Pathology	**Haemorrhagic Stroke**	5 (38%)	-
	Ischemic Stroke	8 (62%)	-
Questionnaire completion method	**Face to face**	8 (62%)	3 (23%)
	Postal Return	4 (31%)	7 (54%)
	Telephone	1 (8%)	3 (23%)

Figure 1 Summary of item reduction for the ArmA



Appendix 1 – Initial list of proposed ArmA items

Passive Function Items
Cleaning the palm affected hand
Cutting fingernails affected hand
Cleaning the around the affected elbow
Cleaning the affected armpit
Cleaning the around unaffected elbow
Putting arm through coat sleeve
Difficulty putting on a glove
Doing physiotherapy exercises to arm
Put on a splint
Position affected arm comfortably
Active Function Items
Difficulty rolling over in bed
Difficulty balancing standing
Difficulty balancing walking
Hold object steady, use other hand (e.g. jar)
Steady myself while standing
Carry an object from place to place
Pick up fork or spoon, use for eating
Comb hair
Pick up cup by handle
Hand craft/card playing
Hold a book for reading
Use towel to dry face or other body part
Pick up a glass
Pick up toothbrush and brush teeth
Shaving / make-up
Use a key to open a door
Letter writing/typing
Poor coffee / tea
Peel fruit or potatoes
Dial number on the phone
Open / close a window
Open an envelope
Take money out of a wallet or purse
Undo buttons on clothing
Buttons on clothing (e.g. shirt, trousers)
Do up a zip (e.g. jacket, trousers)
Undo a zip (e.g. jacket, trousers)

Active Function Items
Tuck in a shirt/blouse
Drink from a cup or mug
Turn on a light with a light switch
Open a drawer
Remove item of clothing from drawer
Pick up phone
Wipe kitchen counter
Get out of car
Open refrigerator
Open a door by turning a door knob
Use a TV remote control
Wash your hands
Turn water on/off with a tap
Dry your hands
Put on your socks
Take off your socks
Put on your shoes
Take off your shoes
Get up from chair with arm rests
Pull chair toward/away from table after/before sitting
Eat half a sandwich or finger food
Use removable computer storage
Hammer a nail
Thread a needle
Wrap gifts
File nails
Cut meat
Peel onions
Shell hazel nuts
Open pack of crisps
Sharpen pencil
Spread butter
Fasten press-stud
Take the cap off a bottle
Open post
Squeeze toothpaste
Unwrap chocolate
Wash hands